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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/488,298	01/20/2000	Olivier Lutz	3874-128 US	4242

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EXAMINER	
KIM, JENNIFER M	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 02/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/488,298	LUTZ ET AL.	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 November 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4 and 7-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4 and 7-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed November 3, 2004 have been received and entered into the application.

Action Summary

The rejection of claims 1, 4 and 7-24 under 35 U.S.C. 112, first paragraph is hereby expressly with drawn in view of Applicants' amendment.

The rejection of claims 1, 4 and 7-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Lambert et al. (U.S.Patent No. 6,458,373B1) of record is withdrawn in view of Applicants' amendment.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4 and 7-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The phrase "at least 99% free of unreacted tocopherol" lack literal support in the specification as filed. This is New Matter rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

It is noted that for the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355 ("PPG could have defined the scope of the phrase consisting essentially of' for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention."). If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. In re De Lajarte, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also Ex parte Hoffman, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989) ("Although consisting essentially of' is typically used and defined in the context of compositions of matter, we find nothing intrinsically wrong with the use of such language as a modifier of method steps. . . [rendering] the claim open only for the inclusion of steps which do not materially affect the basic and novel characteristics of the claimed method. To determine the steps included versus excluded the claim must be read in light of the specification. . . . [I]t is an applicant's burden to establish that a step practiced in a prior art method is excluded from his claims by consisting essentially of' language."). (MPEP 2111.03).

Claims 1, 4 and 7-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Lambert et al. (U.S.Patent No. 6,458,373B1) of record.

Lambert et al. teach a micelle solution or an emulsion with a particle size of 10 to 500 nm comprising chemotherapeutics including podophyllotoxins (etoposide) and their derivatives and analogues, tocopherol and TGPS (d-a-tocopherol polyethylene glycol 1000 succinate). (abstract, column 3, lines 45-58, column 4, lines 1-3, column 7, lines 39-65, column 8, line 59, column 10, lines 28-33, column 21, Example 23).

Lambert et al. teach use of Applicants' water-soluble polymer, polyoxypropylene-polyoxyethylene copoymer in the above composition. (column 3, lines 59-64).

Lambert et al. teach use any compound including peptides, lipid conjugates/prodrugs, and any natural or synthetic molecule which are slightly or completely lipophilic, and any molecules which stimulate the immune system in the above composition. (column 6, lines 54-56).

Lambert et al. teach the amounts of TPGS about 10% in the above composition. (column 21, Example 23).

Lambert et al. teach the concentration of free a-tocopherol in the solution is less than 1.0%, generally less than 0.5%. (column 22, lines 50-60).

Lambert et al. teach that above composition can be administered to treat melanoma tumors in nude mice. (Example 18, table 2).

Applicants' recitation of tocoferol covalently linked to a water-soluble polymer does not represent a patentable limitation since such fails to impart any physical limitation to the composition and it would be inherent in the same composition taught by prior art constituted with same active agents, same formulation (micelle, emulsion), same particle size with same amount of (1.0%) of free tocopherol.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 102(e).

None of the claims are allowed.

Response to Arguments

Applicants' arguments filed November 3, 2004 have been fully considered but they are not persuasive. Applicants argue that Applicants simply exclude from their claims highly impure preparations which by reason of those impurities (by additionally specifying the purity of this disclosed component), might hypothetically read on potentially unpatentable subject matter. This is not persuasive because the amended claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The phrase "at least 99% free of unreacted tocopherol" lack literal support in the specification as filed. Applicants simply did not have possession of the claimed "at least **99% free of unreacted tocopherol**" in the specification as filed. The Examiner only noted that commercially available by Eastmen, Vitamin E TPGS, NF grade comprises 1.5% of free tocopherol is known **not the specific amounts "**at least 99% of unreacted tocopherol". Applicants next argue that claim 1 excludes a surfactant with more than 1% unreacted tocopherol but Lamber teaches composition that requires the addition of unreacted tocopherol (also referred to as a-tocopherol), and in fact, are entirely based on a-tocopherol emulsions. This is not persuasive because there is no support in Applicant's specification that specific purity amount of "unreacted" tocopherol. Further, Lambert teaches the use of a-tocopherol including as a therapeutic agent (column 4, lines 49-65). Therefore, the composition of Lambert clearly encompasses Applicants' claimed

invention. Applicants next argue that the ratio of a-tocopherol to TPGS is optimally from about 1:1 to about 10:1 (w/w), therefore this indicates that Lambert teaches that it is optimal to have as much as ten times as much a-tocopherol than TPGS, but not optimal to have less a-tocopherol than TPGS. This is not persuasive because Lambert teaches the ratio of a-tocopherol to TPGS is from about 1:1 and that Example 26 teaches the concentration of free a-tocopherol in a composition can be less than 1%, generally less than 0.5%, which meets Applicants' claimed invention. Applicants state a third declaration evidencing the surprising nature of the present invention in light of the teachings of Lambert but none of record. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references as cited reference fully teaches same active agent, same amounts of free a-tocopherol and they are drawn to same active agents, same particle size, same formulation (micelle, emulsion).

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sreenivasan Padmanabhan
Supervisory Examiner
Art Unit 1617

1/26/05